

27. Dez. 2004

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To:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

1227 WOODCOCK

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/052377

International filing date (day/month/year)
30.09.2004

Priority date (day/month/year)
01.10.2003

International Patent Classification (IPC) or both national classification and IPC
C07D471/04, A61K31/437, A61K31/444, A61P25/00, A61P29/00, A61P31/00, C07D519/00

Applicant
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Bosma, P

Telephone No. +31 70 340-3665



Box No. 1 Basis of the opinion

- Form PCT/PEA/237 (January 2004)

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 14,15 with respect to IA

because:

- ☒ the said international application, or the said claims Nos. 14,15 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15
	No: Claims	
Inventive step (IS)	Yes: Claims	1-15
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-13
	No: Claims	

2. Citations and explanations

see separate sheet

International Searching Authority

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 14,15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document are referred to in this communication:

D1 : WO 00/49015 A (TAKE KAZUHIKO ;FUJISAWA PHARMACEUTICAL CO (JP);
TOMISHIMA MASAKI () 24 August 2000 (2000-08-24)

Novelty and Inventive step

1) Document D1, which is considered to represent the most relevant state of the art, discloses **pyridine compounds** which are linked to a heterocyclic group such as a **benzimidazolyl group**. The compounds are having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

From this, the subject-matter of the present claims differs in that the present application deals with **pyridin-2-yl-alkylene-3H-imidazo[4,5-b]pyridine** derivatives, which compounds are also having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

The subject-matter these claims is therefore novel (Article 33(2) PCT)

2) The problem to be solved by the present invention may be regarded as the provision of further compounds that are having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

The solution to this problem proposed in the claims of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The present **imidazo[4,5-b]pyridine** derivatives of formula (I) are structurally very remote from any of the available prior art compounds having the same use and it is therefore considered that there were no incentives from this prior art to use the above described **pyridin-2-yl-alkylene-3H-imidazo[4,5-b]pyridine** derivatives as nitric oxide synthase inhibitors.

Industrial applicability

For the assessment of the present claims 14,15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.
(see also Box III above).